

Remarks/Argument

The Applicant's representative thanks the Examiner for her helpful comments during the telephonic interview of February 4, 2005.

Claims 45-54, 59, 60, 65-77 and 97-106 are pending in the application. Claims 45, 51, 52, 53, 71, 74 and 76 have been amended. In this amendment, claims 50, 59-60, 72-73, 75, 77, 99-103 have been cancelled without prejudice to the filing of a continuing application. Upon entry of this amendment, claims 45-49, 51-54, 65-71, 74, 76, 97-98 and 104-106 will be pending in the application.

Claim 45 has been amended to remove the word "mucopolysaccharide" in front of the phrase "extracellular matrix compound." The compounds glycosaminoglycan, collagen, cartilage, chondroitin sulfate, glycoprotein, and proteoglycan are defined in dependent claim 53 as "extracellular matrix compounds." The attached pages from The Molecular Biology of the Cell, Alberts et al. (Eds.), Garland Publ., Inc., New York, 1983, pp. 692-693 and 702 show that these compounds are indeed extracellular matrix compounds.

Claims 51, 71, 74 and 76 have been amended for clarity as suggested by the Examiner. The scope of these claims has not been changed by these amendments, and no new matter has been added.

Response to the Claim Objection

Claim 53 was objected to for containing a mis-spelling of the word "proteoglycan." Claim 53 has been amended to correct this error. The spelling of "glycosaminoglycan" was also corrected in claim 53.

Response to Section 101 Rejection

Claims 59-60, 72, 75, 99-101 and 103 are rejected under 35 U.S.C. 101 as allegedly lacking utility. In the interests of advancing prosecution, these claims have been canceled without prejudice to the filing of a continuing application. This rejection is therefore moot.

Response to Section 112, 1st Paragraph Rejection

Claims 59-60, 72, 75, 99-101 and 103 are rejected under 35 U.S.C. 112, 1st paragraph as allegedly lacking written description. In the interests of advancing prosecution, these claims have been canceled without prejudice to the filing of a continuing application. This rejection is therefore moot.

Claims 45-54, 65-71, 73-74, 76-77, 97-98 and 104-106 are rejected under 35 U.S.C. 112, 1st paragraph as allegedly lacking written description for medicaments comprising an anabolic medicament for treating damaged tissue, comprising at least one extracellular matrix compound in an amount which is effective to act as an anti-neo-inflammatory and anti-neo-angiogenetic agent; at least one polar surface active lipid; and a plurality of amino acids, no more than 10% of which are in the D-form, in a molar ratio which is characteristic of healthy human breast tissue. In the interest of advancing prosecution, claims 50, 73 and 77 have been canceled without prejudice to the filing of a continuing application, and the rejection is moot as to these claims. The rejection will be discussed with respect to claims 45-49, 51-54, 65-71, 74, 76, 97-98 and 104-106.

Claim 45 has been amended without prejudice to recite the molar ratio of the plurality of amino acids is characteristic of human breast milk protein. Claims 54, 65-71, 74, 76, 97-98 and 104-106, which depend either directly or indirectly from claim 45, also recite the molar ratio of the plurality of amino acids is characteristic of human breast milk protein. The claimed embodiment of the present medicaments where the L-amino acids are present in a ratio characteristic of human breast milk protein is fully described.

To comply with the written description requirement, a specification must convey to one skilled in the art that the applicant had possession of the claimed invention. Information which is well known in the art need not be described in detail in the specification. See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986).

The ratio of L-amino acids in human breast milk proteins was known to one of skill in the art as of the filing date of the present application. For example, the infant nutritional supplement Neocate® (available from SHS North America, Gaithersburg, MD) contains proportions of L-amino acids based on human breast milk. See, e.g., page 2 of the printout of Bines et al., 1998, *J. Pediatr. Gastroenterol. and Nutr.* 26(2): 123-128 and Table 2 therein, submitted with the Amendment filed October 14, 2004. As stated on Bines et al., pg. 2:

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The study formula was a nutritionally complete infant formula (Neocate; Scientific Hospital Supplies, Liverpool, UK) composed of synthetic L-amino acids with proportions based on the amino acid profile of human breast milk.

The amino acid ratio of human breast milk protein was therefore well-known at least as of 1998, as evidenced by Bines et al.

The present specification describes and discloses the embodiment of the present medicament in which the L-amino acids are present in the amino acid ratio of human breast milk. Moreover, examples are presented in the specification where Neocate being used to make the claimed compositions (as discussed in the Oct. 14 Amendment). This description and disclosure is sufficient to show one skilled in the art that the Applicant had possession of the composition recited in claim 45 and its dependent claims. As stated by the Examiner on pg. 6 of the Office Action, "those embodiments described and disclosed meet the written description requirement."

Thus, the Applicants submit that claim 45, and its dependent claims 54, 65-71, 74, 76, 97-98 and 104-106, comply with the written description requirement, and respectfully request withdrawal of the section 112, 1st paragraph rejection of these claims.

Response to section 112, 2nd paragraph rejections

Claims 45-54, 65-71, 73-74, 76-77, 97-98, 102 and 104-106 are rejected under 35 U.S.C. 112, 2nd paragraph as allegedly being indefinite for reciting that the L-amino acids are present in a molar ratio which is characteristic of healthy human breast tissue. In the interest of advancing prosecution, claims 50, 73, 77 and 102 have been canceled without prejudice to the filing of a continuing application, and the rejection is moot as to these claims. The rejection will be discussed with respect to claims 45-49, 51-54, 65-71, 74, 76, 97-98 and 104-106.

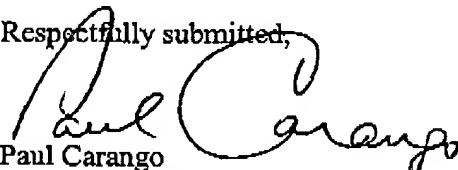
Claim 45 has been amended without prejudice to recite the molar ratio of the plurality of amino acids is characteristic of human breast milk protein. Claims 54, 65-71, 74, 76, 97-98 and 104-106, which depend either directly or indirectly from claim 45, also recite the molar ratio of the plurality of amino acids is characteristic of human breast milk protein. Thus, amended claim 45 is clear as to which protein is the basis for the claimed molar ratio. The Applicant respectfully

requests withdrawal of the section 112, 2nd paragraph rejection of claims 45-49, 51-54, 65-71, 74, 76, 97-98 and 104-106.

Conclusion

Based on the foregoing, all claims are believed to be in condition for allowance. An early action toward that end is earnestly solicited.

Respectfully submitted,



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